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EXAMINER	
GWARTNEY, ELIZABETH A	
ART UNIT	PAPER NUMBER
1794	
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/588,320	SCHLOTHAUER ET AL.	
	Examiner	Art Unit	
	Elizabeth Gwartney	1794	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-38* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-38* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *20090515;20081126;20070711;20060803*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claim Objections

1. Claims 1-2, 4, 10-11, 13, 16, 30 and 34 are objected to because of the following informalities:

- Regarding claims 1-2, 4, 10-11, 13, 16, and 30, the hyphen in the term "micro-organism" should be eliminated. Appropriate correction is required.

- Regarding claim 34, the period at the end of line 1 is improper. Appropriate correction is required.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

3. Claim 37 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Since the microorganism(s) is/are essential to the claimed invention it must be obtainable by a repeatable method set forth in the specification or otherwise be readily available to the public. If the microorganism(s) is/are not so obtainable or available, the requirements of 35 USC 112 may be satisfied by deposit(s) of the microorganism(s). The specification does not disclose

a repeatable process to obtain the microorganism(s) and it is not clear from the specification or record that the microorganism(s) is/are readily available to the public.

This rejection may be overcome by establishing that the each microorganism identified is readily available to the public and will continue to be so for a period of 30 years or 5 years after the last request or for the effective life of the patent, whichever is longer, or by an acceptable deposit as set forth herein.

If the depository is made under the terms of the Budapest Treaty, then an affidavit or declaration by applicants, or a statement by an attorney of record over his/her signature and registration number, stating that the specific strain has been deposited under the Budapest Treaty and that the strain will be irrevocably and without restriction or condition released to the public upon the issuance of a patent, would satisfy the deposit requirement made herein.

If the deposit has not been made under the Budapest Treaty, then in order to certify that the deposit meets the criteria set forth in 37 CFR 1.801-1.809, applicants may provide assurance of compliance by an affidavit or declaration, or by a statement by an attorney over his/her registration number, showing that,

(a) during the pendency of the application, access to the invention will be afforded to the Commissioner upon request;

(b) all restrictions upon availability to the public will be irrevocably removed upon the granting of the patent;

(c) the deposit will be maintained in a public depository for a period of 30 years or 5 years after the last request or for the effective life of the patent, whichever is longer; and,

(d) the deposit will be replaced if it should ever become inviable.

The specification must also state the date of deposit(s), the number(s) granted the deposit(s) by the depository and the name and address of the depository.

Claim Rejections - 35 USC § 112/ 35 USC § 101

4. 35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

5. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

6. Claims 16, 29 and 33-36 are rejected under 35 U.S.C. 101 because the claimed recitation of a use, without setting forth any steps involved in the process, results in an improper definition of a process, i.e., results in a claim which is not a proper process claim under 35 U.S.C. 101. See for example *Ex parte Dunki*, 153 USPQ 678 (Bd.App. 1967) and *Clinical Products, Ltd.* v. *Brenner*, 255 F. Supp. 131, 149 USPQ 475 (D.D.C. 1966).

7. Claims 6-17, 19-26, 29, 33-36 and 38 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 6 recites the limitation "said EPS production" in line 2. There is insufficient antecedent basis for this limitation in the claim. While claim 1 requires an EPS fermentation culture that is capable of producing an enzyme that is capable of producing EPS, there is nothing in claim 1 that requires a composition with EPS.

Regarding claim 13, the recitation "*can be* selected from the group consisting of" renders the claim indefinite because it is unclear whether this further limits the claim, since there is no positive recitation that the microorganism is one of the recited ones, or if it can be another.

Claim 16 provides for the use of a composition to prepare a cheese product, but, since the claim does not set forth any steps involved in the method/process, it is unclear what method/process applicant is intending to encompass. A claim is indefinite where it merely recites a use without any active, positive steps delimiting how this use is actually practiced.

Regarding claim 17, the recitation "prepared by using the composition" renders the claim indefinite since it is unclear as to whether the cheese product actually contains this composition or is somehow simply "used."

Regarding claim 19, the recitation "capable of modulating the moisture content" renders the claim indefinite because it is unclear how this is accomplished. Further, it is unclear how this further limits the previous claim, since addition of nearly any material would be expected to modulate, i.e. modify, the moisture content.

Claims 19, 21, 24 and 26 recite the limitation "said EPS". There is insufficient antecedent basis for this limitation in the claims.

Regarding claim 20, the recitations "capable of being achieved" and "optimizing" render the claim indefinite because it is not clear how the whey release is optimized.

Regarding claim 21, the recitation "wherein said EPS increases the stability" renders the claim indefinite because it is not clear what is encompassed by the term "stability", i.e. color stability, microbial stability.

The term "greater resilience" in claim 22 is a relative term which renders the claim indefinite. The term "resilience" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. Further, it is not clear what type of "resilience" is intended, how it is measured, and to what it is measured relative to.

Regarding claim 23, the recitation "capable of being manipulated" renders the claim indefinite because it is unclear how this is accomplished.

Regarding claim 24, the recitation "capable of forming a cheese curd containing about 50% moisture content" renders the claim indefinite because it is unclear how this is accomplished.

Regarding claim 26, the recitation "capable of improving at least one of the texture, aroma, flavor . . of the cheese product" renders the claim indefinite because it is unclear how this accomplished and what the properties of the cheese product are being compared.

Claim 29 provides for the use of a composition to modulate microbial balance of the gastrointestinal tract after consumption of said cheese product, but, since the claim does not set forth any steps involved in the method/process, it is unclear what method/process applicant is intending to encompass. A claim is indefinite where it merely recites a use without any active, positive steps delimiting how this use is actually practiced.

Claims 33-36 provide for the use of EPS, but, since the claim does not set forth any steps involved in the method/process, it is unclear what method/process applicant is intending to encompass. A claim is indefinite where it merely recites a use without any active, positive steps delimiting how this use is actually practiced.

Regarding claim 34, the recitation "capable of improving at least one of the . .." renders the claim indefinite because it is unclear how this is accomplished.

Claim 38 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite in that it fails to point out what is included or excluded by the claim language. This claim is an omnibus type claim.

Claim Rejections - 35 USC § 102

8. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

9. Claims 1-15, 17-28, 30-32 and 37-38, are rejected under 35 U.S.C. 102(b) as being anticipated by Perry et al. ("Effect of Exopolysaccharide-Producing Cultures on Moisture Retention in Low Fat Mozzarella Cheese").

Regarding claims 1-8, Perry et al. disclose a starter culture composition for making cheese comprising *Streptococcus thermophilus* and *Lactobacillus delbrueckii* (Abstract, p.800/Materials and Methods/Milk and Cultures).

Given Perry et al. disclose that said lactic acid microorganisms are capable of producing an exopolysaccharide (EPS) (Abstract, p.799/Introduction/paragraph 3), it is clear that they inherently are capable of producing an enzyme that is capable of producing EPS.

Further, given Perry et al. disclose lactic acid bacterium, *Streptococcus thermophilus* and *Lactobacillus delbrueckii*, it is clear that the lactic acid bacterium would inherently be capable of fermenting lactic acid.

Regarding the method limitations recited in claims 6-8, it is noted that even though a product-by-process is defined by the process steps by which the product is made, determination of patentability is based on the product itself. *In re Thorpe*, 777 F.2d 695, 227 USPQ 964 (Fed. Cir. 1985). As the court stated in *Thorpe*, 777 F.2d at 697, 227 USPQ at 966 (The patentability of a product does not depend on its method of production. *In re Pilkington*, 411 F.2d 1345, 1348, 162 USPQ 145, 147 (CCPA 1969). If the product in a product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process.). In this case, claim 1 requires a composition comprising a EPS fermentation culture which contains a viable lactic acid microorganism capable of producing EPS. In this case, Perry et al. disclose a composition identical to that presently claimed.

Regarding claims 9 and 12, Perry et al. disclose all of the claim limitations as set forth above. Given Perry et al. disclose a composition identical to that presently claimed wherein the lactic acid bacterium is capable of producing EPS, since claim 1 does not require EPS as part of the composition, the limitations of claims 9 and 12 have been met.

Regarding claims 17-18, Perry et al. disclose all of the claim limitations as set forth above. Further, Perry et al. disclose low fat Mozzarella cheese prepared using the composition of claim 1 (Abstract, p.800-801/Manufacturing Procedure & Cheese Analysis).

Regarding claims 19, Perry et al. disclose all of the claim limitations as set forth above and that the EPS cultures are useful to increase moisture retention in low fat Mozzarella cheese (p.804/Conclusions).

Regarding claims 20-25, Perry et al. disclose all of the claim limitations as set forth above. Regarding the method limitations recited in claims 20-25 it is noted that even though a product-by-process is defined by the process steps by which the product is made, determination of patentability is based on the product itself. *In re Thorpe*, 777 F.2d 695, 227 USPQ 964 (Fed. Cir. 1985). As the court stated in *Thorpe*, 777 F.2d at 697, 227 USPQ at 966 (The patentability of a product does not depend on its method of production. *In re Pilkington*, 411 F.2d 1345, 1348, 162 USPQ 145, 147 (CCPA 1969). If the product in a product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process.). In this case, Perry et al. disclose a cheese product identical to that presently claimed, thus the patentability of the cheese product does not depend on its method of production.

Regarding claim 26, Perry et al. disclose all of the claim limitations as set forth above. Given Perry et al. disclose a cheese product identical to that presently claimed, it is clear that that the cheese product would inherently display the recited improved sensory, nutrition, and/or physical properties.

Regarding claim 27, Perry et al. disclose a method of forming a Mozzarella cheese comprising adding the composition of claim 1 to milk, forming a cheese curd (p.800/Manufacturing Procedure). Perry et al.also disclose a ripened cheese product with about 60% moisture (p.800/Table 1/Starter 4). Given Perry et al. disclose a method for forming

Mozzarella cheese using a composition identical to that presently claimed, it is clear that the cheese curd would inherently contain about 50% moisture and lose less that 5% moisture as a result of ripening.

Regarding claim 28, Perry et al. disclose all of the claim limitations as set forth above and a cheese product (Abstract, p.801/Manufacturing Procedure).

Regarding claims 30, Perry et al. disclose all of the claim limitations as set forth above. Perry et al. also disclose a process for in situ production of EPS comprising providing a starter culture composition according to claim 1, inoculating vats of milk with the starter culture composition and ripening (i.e. permitting the growth of the microorganisms). Given Perry et al. disclose EPS forming microorganisms identical to those of the present invention, it is clear that the microorganisms would inherently produce EPS.

Regarding claim 38, Perry et al .disclose a Mozzarella cheese product (Abstract).

Claim Rejections - 35 USC § 103

10. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

11. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.

2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

12. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

13. Claims 10-11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Perry et al. ("Effect of Exopolysaccharide-Producing Cultures on Moisture Retention in Low Fat Mozzarella Cheese").

Regarding claim 10, Perry et al. disclose all of the claim limitations as set forth above. While Perry et al. disclose *Streptococcus thermophilus* TA061, the reference does not explicitly disclose the V3 strain. However, given Perry et al. disclose the TA061 strain produces EPS, it would have been obvious to one of ordinary skill in the art to have used any strain of *Streptococcus thermophilus* known to produce EPS, including the V3 strain, and arrive at the present invention.

Regarding claim 11, Perry et al. disclose all of the claim limitations as set forth above. Perry et al. also disclose an adjunct culture comprising EPS producing *Lactococcus lactis ssp. Cremoris* . While Perry disclose Lactococcus lactis ssp. Cremoris, the reference does not explicitly disclose the 322 strain. However, given Perry et al. disclose *Lactococcus lactis ssp.*

Cremoris produces EPS, it would be obvious to one of ordinary skill in the art to have used any strain of *Lactococcus lactis ssp. Cremoris* known to produce EPS, including the 322 strain, and arrive at the present invention.

14. Claims 13-14 and 32 are rejected under 35 U.S.C. 103(a) as being unpatentable over Perry et al. ("Effect of Exopolysaccharide-Producing Cultures on Moisture Retention in Low Fat Mozzarella Cheese") and further in view of Degeest et al. ("Exopolysaccharide (EPS) biosynthesis by *Lactobacillus sakei* 0-1: production kinetics, enzyme activities and EPS yields").

Regarding claims 13-14 and 32, Perry et al. disclose all of the claim limitations as set forth above. While Perry disclose EPS producing lactic acid bacterium, *Streptococcus thermophilus* and *Lactobacillus delbrueckii*, the reference does not explicitly disclose a culture selected from the recited group.

Degeest et al. teach that *Lactobacillus sakei* strains are known producers of EPS in food systems (p. 470-471/Abstract, Introduction).

Perry et al. and Degeest et al. are combinable because they are concerned with the same field of endeavor, namely, EPS producing lactic acid bacterium. Given Degeest et al. teach that *Lactobacillus sakei* strains are known producers of EPS, it would have been obvious to one of ordinary skill in the art at the time of the invention to have used any EPS producing lactic acid bacterium, including *Lactobacillus sakei*, and arrive at the present invention.

Regarding strain, while Degeest et al. teach *Lactobacillus sakei* 0-1, the reference does not explicitly disclose the 570 strain. However, given Degeest et al. teach the 0-1 strain produces EPS, it would have been obvious to one of ordinary skill in the art to have used any

strain of *Lactobacillus sakei* known to produce EPS, including the 570 strain, and arrive at the present invention.

15. Claim 15 and 31 are rejected under 35 U.S.C. 103(a) as being unpatentable over Perry et al. ("Effect of Exopolysaccharide-Producing Cultures on Moisture Retention in Low Fat Mozzarella Cheese") and further in view of Tallgren et al. ("Exopolysaccharide-Producing Bacteria from Sugar Beets").

Regarding claims 15 and 31, Perry et al. disclose all of the claim limitations as set forth above. While Perry disclose EPS producing lactic acid bacterium, *Streptococcus thermophilus* and *Lactobacillus delbrueckii*, the reference does not explicitly disclose *Leuconostoc mesenteroides* or a bacterium that produces a homo-EPS.

Tallgren et al. teach that *Leuconostoc mesenteroides* strains are known producers of EPS (p. 862/Abstract, Introduction). Given Tallgren et al. teach *Leuconostoc mesenteroides*, it is clear that the bacterium would intrinsically produce a homo-EPS.

Perry et al. and Tallgren et al. are combinable because they are concerned with the same field of endeavor, namely, EPS producing lactic acid bacterium. Given Tallgren et al. teach that *Leuconostoc mesenteroides* strains are known producers of EPS, it would have been obvious to one of ordinary skill in the art at the time of the invention to have used any EPS producing lactic acid bacterium, including *Leuconostoc mesenteroides*, and arrive at the present invention.

Regarding strain, while Tallgren et al. teach 2 different *Leuconostoc mesenteroides* strains, the reference does not explicitly disclose the 808. However, given Tallgren et al. teach the strains produce EPS, it would have been obvious to one of ordinary skill in the art to have

used any strain of *Leuconostoc mesenteroides* known to produce EPS, including the 808 strain, and arrive at the present invention.

16. Claim 37 is rejected under 35 U.S.C. 103(a) as being unpatentable over Degeest et al. ("Exopolysaccharide (EPS) biosynthesis by Lactobacillus sakei 0-1: production kinetics, enzyme activities and EPS yields").

Regarding claim 37, Degeest et al. disclose a culture of Lactobacillus sakei 0-1 (p. 471/Materials and Methods). Given Degeest et al. disclose a Lactobacillus sakei culture, since *Lactobacillus sakei* strains are known to produce EPS (p.470-471/Abstract, Introduction), it follows that the Lactobacillus sakei 0-1 and *Lactobacillus sakei* DSM 15889 are interchangeable.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Elizabeth Gwartney whose telephone number is (571) 270-3874. The examiner can normally be reached on Monday - Friday;7:30AM - 3:30PM EST..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Keith Hendricks can be reached on (571) 272-1401. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/E. G./
Examiner, Art Unit 1794

/Keith D. Hendricks/
Supervisory Patent Examiner, Art Unit 1794